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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/649,582 | BRUGGER ET AL. | |
| | Examiner | Art Unit | |
| | LESLIE R. DEAK | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,5-10,12,14 and 16-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10,12,14 and 16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

1. Claim 23 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 21. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 21 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 30 sets forth the limitation that the “only”

flow regulating device between the connectors and the blood portion is a single pumping portion between the blood portion and the junction. However, Applicant's specification clearly indicates that downstream of the replacement fluid junction and filter there is a clamping portion 190 that engages with a clamp 188 on machine 16 before reaching pump header region 200. Therefore, the pump is NOT the only flow regulating device between the fluid replacement junction and the venous connection.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 5-10, 12, 14, 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/37786 to Burbank in view of US 5,476,592 to Simard

In the specification and figures, Burbank discloses the apparatus substantially as claimed by applicant. With regard to claims 1, 19, and 26, Burbank discloses a disposable fluid circuit for use in extracorporeal treatment systems comprising a fluid circuit mounted in a cartridge 18 with a blood portion 62/78, 64/84 with a porous membrane or hemofilter 34 connected therein (see p 16, 19). The circuit further comprises a replacement fluid portion 172 that connects to a source of replacement fluid 176 wherein the replacement fluid portion may comprise a sterilizing filter 178 (see p22). In an embodiment, the replacement fluid portion may comprise a plurality of connectors 294 joined at a junction (unlabeled) to flow through the sterilizing filter 178

into the replacement fluid portion (see FIG 21) without any intervening flow regulating portion. The plurality of connectors may be connected to replacement fluid containers with a content of 8L of fluid, wherein each container contains the same replacement fluid (see p22).

Burbank fails to disclose that the sterilizing filter comprises a pore size effective to eliminate pyrogens from a fluid passing therethrough. However, Simard discloses a hemofiltration apparatus comprising a replacement fluid line 22 with a filter 24 with a porosity sufficient to remove pyrogens from the replacement fluid in order to prevent undesirable elements from passing to the patient (see columns 2-3, FIG). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a filter with a pore size sufficient to eliminate pyrogens (specifically, 0.22 μm, see column 3, lines 56-62) from fluid as disclosed by Simard to the fluid circuit with replacement fluid disclosed by Burbank in order to prevent passing undesirable elements to the patient.

With regard to claims 3,12, 21, 23, the circuit comprises a tray or cartridge 18 that supports the blood, filtrate, and replacement fluid paths (see p14).

With regard to claims 5, 14, 22, Burbank illustrates that the connectors may comprise a plurality of bag spikes (see FIG 21).

With regard to claim 6, as best determined by the Examiner, the sterilizing filter 178 is located in the replacement fluid line such that all replacement fluid passes through the filter 178 (see FIG 21).

With regard to claims 7-8, 16-17, 24-25, Burbank discloses that the circuit is configured to carry blood, waste (filtrate), and replacement fluid during hemofiltration (see p15, lines 32-35), including fluid flow paths, valve paths, and pumping portions that are arranged in the cassette 18 to align with their respective actuators (see p16).

With regard to claim 9, Burbank discloses that the replacement fluid is selected to maintain the patient's normal electrolyte balance (see p35, lines 25-27).

With regard to claims 10 and 18, Burbank discloses arterial and venous blood connections (see p18, line 31 to p 19, line 35), and that the sterilizing filter is located in the replacement fluid line (see FIG 21) and that the replacement fluid line is connected to the venous line 64 (see p 22, lines 30-35).

With regard to claim 27, it appears from FIG 21 provided by Burbank that the connector leads at 294 are connected to the filter 178 by substantially similar lengths of tubing, which is the same illustration provided by Applicant. Accordingly, it is the position of the Examiner that the length of tubing claimed and illustrated by Applicant is shown in the Burbank device.

With regard to claims 28-29, Burbank illustrates that the filtration set 191, comprising connector leads that feed into a common line and the filter, connects to fluid circuit in cassette 18 via input connector 174 (see FIG 21).

With regard to claim 30, Burbank discloses and illustrates a clamping region 190 that communicates with clamp 188 downstream of the fluid replacement junction, in addition to pump region 200 before the connection with the blood portion of the circuit. However, it has been held that the omission of an element and its function is obvious if

the function of the element is not desired. See MPEP § 2144.04(II)(A). In the instant case, it is the position of the Examiner that eliminating the clamp and its fluid control function in the device disclosed by Burbank would have been obvious to one of ordinary skill of art at the time of invention, since the fluid control function is not desired.

### *Response to Arguments*

6. Applicant's amendment and arguments filed 3 October 2007 have been entered and considered.

7. Applicants arguments with respect to the pending claims have been considered but are moot in view of the new grounds of rejection presented above.

### *Conclusion*

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
6 March 2008